



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

May 11, 2004

Bert W. Rein
Wiley Rein & Fielding LLP
1776 K Street NW
Washington, District of Columbia 20006

Dear Mr. Rein:

Your petition submitted on behalf of Pfizer Inc., requesting the Food and Drug Administration to adhere to the statutory limitations of section 505(j)(5)(B)(iv) of the Act in issuing final approvals to ANDA applicants, was received by this office on 05/11/2004. It was assigned docket number 2004P-0227/CP1 and it was filed on 05/11/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the typed name and title.

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0227

ACK 1